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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/454,529 05/30/95 HOGAN

J 212/083

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HM22/0423

EXAMINER

MARSCHER, A

ART UNIT	PAPER NUMBER
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1631

DATE MAILED:

3  
04/23/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.

08/454,529

Applicant(s)

Hogan et al.

Examiner

Ardin Marschel

Art Unit

1631



— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

1) ☒ Responsive to communication(s) filed on Feb 5, 2001

2a) ☐ This action is FINAL.

2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

4) ☒ Claim(s) 486-630 is/are pending in the application.

4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.

6) ☒ Claim(s) 486-608, 611-622, 629, and 630 is/are rejected.

7) ☒ Claim(s) 609, 610, and 623-628 is/are objected to.

8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some\* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.

2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

15) ☒ Notice of References Cited (PTO-892) (2 sheets)

18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_\_

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

19) ☐ Notice of Informal Patent Application (PTO-152)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_

20) ☐ Other: \_\_\_\_\_

Applicants' arguments, filed 2/5/01, have been fully considered and they are deemed to be persuasive to overcome the previous rejections in the office action, mailed 10/2/00. Specifically, the instant invention has been persuasively argued as being directed to variable regions in ribosomal sequences which are usable over many target organisms, each such organism containing ribosomal sequences specific thereto, respectively. The target sequence in said region(s) in each target organism is reasonably available either as instantly disclosed, disclosed in various ribosomal sequence publications, or via routine experimentation with comparison to corresponding *E. coli* ribosomal sequences. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. However, upon reconsideration, the following rejections and/or objections are newly applied. They constitute the complete set presently being applied to the instant application.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to

be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 486-491, 514, 515, 563, 564, 573, and 574 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 8-17 of U.S. Patent No. 5,958,679. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms as claimed in said Patent for region 305-340 of 23S rRNA of *Enterobacter cloacae*. The instant claims include regions 270-405 or 270-390 or overlapping regions of 23S rRNA, thus being generic to the 305-340 region. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as

specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 506, 507, 547, 548, 553, and 554 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 17-25 of U.S. Patent No. 5,994,059. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to region 825-860 of 16S rRNA or portions thereof regarding certain Streptococcus species. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism

selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 500, 501, 504, 505, 508, 509, 593-598, and 601-606 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-38 of U.S. Patent No. 5,674,684. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions 405-428, 440-475, 705-735, and 980-1010 of 16S rRNA or portions thereof regarding certain *Campylobacter* species. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of

specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 514, 515, 571, and 572 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-20 of U.S. Patent No. 5,677,127. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to region 365-405 of 23S rRNA or portions thereof regarding group I Pseudomonas species. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same

set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 494, 495, 498, 499, 502, 503, 514, 515, 518-523, 528, 529, 532, 535, 536, 545-550, 563-568, 577, 578, and 581-590 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 51-90 of U.S. Patent No. 5,693,468. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof as listed in claim 51 of said Patent directed to Chlamydia trachomatis detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both



copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-493, 498-501, 506, 507, 512, 513, 526, 527, 532, 537-542, 547, 548, 551, 552, 561, and 562 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 29-55 of U.S. Patent No. 5,691,149. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof as listed in claim 29 of said Patent directed to *Mycoplasma pneumoniae* detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target

organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 508, 509, and 555-558 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-24 of U.S. Patent No. 5,693,469. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to the region of rRNA or portions thereof as listed in claim 16 of said Patent directed to *Escherichia coli* detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target

organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 514, 515, 563, 564, 569, and 570 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-24 of U.S. Patent No. 5,683,876. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to the region of rRNA or portions thereof as listed in claim 16 of said Patent directed to *Proteus mirabilis* detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for

definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 498, 499, and 532-534 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-22 of U.S. Patent No. 5,595,874. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof directed to 16S rRNA region 185-225 of said Patent directed to Mycobacterium intracellulare detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal

regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 498, 499, and 532-534 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 16-22 of U.S. Patent No. 5,593,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof directed to 16S rRNA region 185-225 of said Patent directed to *Mycobacterium avium* detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing

them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 510, 511, 514, 515, 611-614, 617, and 618 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-37 of U.S. Patent No. 5,714,321. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof directed to 16S rRNA region 1125-1155 and 23S rRNA region 335-375 of said Patent directed to Salmonella species detection. The instant specification must be consulted for the target organisms

which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 498, 499, 516-519, 524, 525, 532-534, 575, 576, 579, 580, 591, and 592 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 34-55 of U.S. Patent No. 5,547,842. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA as listed in claim 34 of said Patent directed to Mycobacterium species detection. The instant specification must be consulted

for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 504, and 505 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 36-64 of U.S. Patent No. 5,679,520. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof directed to 16S rRNA region 675-715 of said Patent directed to eubacteria detection. The



instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 502, 503, 508, 509, 514, 515, 520, 521, 524, 525, 599, 600, 603, 604, 607, 608, 613-616, 619-622, 629, and 630 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 25-48 of U.S. Patent No. 5,677,129. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof as

listed in claim 25 of said Patent directed to Legionella species detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

Claims 486-491, 496, 497, 500, 501, 508, 509, 530, 531, 539, 540, 543, 544, 559, and 560 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 330-337 and 386-399 of copending U.S. application Serial No. 08/255,990. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims are generic claims inclusive of methods directed to species therein which are directed to specific ribosomal regions and target organisms. It

is noted that common region species between the respective claims are those directed to regions of rRNA or portions thereof directed to 16S rRNA regions 125-150, 455-485, and 980-1015 of said copending application directed to *Neisseria gonorrhoeae* detection. The instant specification must be consulted for the target organisms which are specifically target species since they are not listed in most of the instant claims. The lack of listing them in most of the instant claims regarding ribosomal regions clearly motivates looking to the specification for definition of such target organisms. It is noted that the instant specification and that of the cited Patent are both copies of the same parent application Serial Number 07/806,929 and therefore both include a description of the same set of specific target organism selections and ribosomal regions as specifically described species. It is noted that such specifically described species are deemed both suggested and motivated within generic claims or disclosures in an obviousness-type rejection of this type.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 609, 610, and 623-628 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of

the base claim and any intervening claims.

The potential interference will be reconsidered after resolution of the above issues.

No claim is allowed.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703)308-0196.

April 20, 2001

*Ardin H. Marschel*  
**ARDIN H. MARSCHEL**  
**PRIMARY EXAMINER**